

**GUIDANCE FOR ASSESSING CHEMICAL CONTAMINATION DATA  
FOR USE IN FISH ADVISORIES**

**VOLUME III: OVERVIEW OF RISK MANAGEMENT**

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Washington, DC

## EXECUTIVE SUMMARY

State, local, and federal agencies currently use various methods to estimate risks to human health from the consumption of chemically-contaminated, non-commercial fish. A 1988 survey, funded by the U.S. Environmental Protection Agency (EPA) and conducted by the American Fisheries Society, identified the need for a standardized approach to evaluating risks and developing fish consumption advisories to provide comparable advisories across different jurisdictions (RTI, 1990). Four key components were identified as critical to the development of a consistent risk-based approach: standardized practices for sampling and analyzing fish, standardized risk assessment methods, standardized procedures for making risk management decisions, and standardized approaches to risk communication (RTI, 1990).

To address concerns raised by the survey respondents, EPA has developed a series of four documents designed to provide guidance to state, local, regional, and tribal environmental health officials responsible for issuing fish advisories. The documents are designed as guidance only and do not constitute a regulatory requirement. The documents are:

*Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories*

*Volume I: Fish Sampling and Analysis*

*Volume II: Risk Assessment and Fish Consumption Limits*

*Volume III: Risk Management*

*Volume IV: Risk Communication*

It is essential that all four documents be used together, since no single volume addresses all of the topics involved in the development of risk-based fish consumption advisories.

Fish contamination has become a recognized health hazard in some areas in recent

years. While most fish provide an excellent source of nutrition, some fish are sufficiently contaminated to generate health risks (e.g., Minamata disease in Japan). The responsibility for safeguarding the public from contaminated fish is shared by different agencies in the United States. Federal agencies such as the United States Food and Drug Administration (FDA)<sup>1</sup> have responsibility for advisories regarding commercial fish. EPA, the Department of Energy, and the United States Fish and Wildlife Service, are also involved in managing and monitoring waterbodies, controlling pollutant releases, and managing clean up and remediation efforts that impact fish contaminant concentrations. Responsibility for safeguarding the public against effects of contaminants in non-commercial fish falls to state, local, and tribal agencies and groups. The overall objective of this series is to provide guidance to these agencies and groups regarding the development of fish advisories for non-commercial fish.

The field of risk management, as it deals with fish advisories, is a relatively new and evolving area. A few states have long-standing advisory programs; however, written evaluations of these programs were not available for the most part. Consequently, there is limited information available from which to draw conclusions or guidance regarding management strategies. Examples of types of advisories were obtained from ongoing advisory programs. Advisory program staff were consulted regarding their experiences with various management approaches. Due to the information constraints, this document provides an overview of risk management rather than detailed and highly specific guidance. Numerous state and local advisory programs have recently been developed, and it is anticipated that additional information will be available in future editions of this volume.

A variety of options exist for managing health risks through fish advisories. Options for limiting consumption of contaminated fish range from approaches requiring limited resources to resource-intensive approaches such as the development of quantitative health-based advisories. This document presents various options that may be used in fish advisory programs, with a discussion of the types of information and resources required and their advantages and disadvantages. A discussion is included of specific characteristics that may be considered when developing a fish advisory program, including: contaminant and risk levels, resources available for program development, the feasibility and efficacy of the options, and the anticipated impacts of various options on target populations (e.g., on nutrition, economics, traditional activities, communities, risk). A structure for organizing information on options and characteristics is provided and a tiered approach to developing fish advisories is discussed. Templates are included to enable risk managers to organize their information to evaluate needs and to identify the optimal group of options and consumption limits for their area.

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<sup>1</sup> See the Glossary for definitions of abbreviations and selected terms.

The risk management approach discussed in this volume includes a discussion of critical decisions required to carry out sampling and analysis, risk assessment, and advisory program development. This highlights for the risk manager those decisions that may have a significant impact on risk estimates and the corresponding advisories. The uncertainties inherent in these decisions are also discussed.

Environmental justice is discussed in this volume because contaminated fish may be consumed in greater quantities by minorities and low-income populations in many areas of the United States. These groups are often subsistence fishers (fishers who rely substantially on fish they catch as a food source) and may be simultaneously exposed to the pollutant found in their fish via other sources as well (in other foods, air, and water). Subsistence fishers live in urban environments, where high pollution levels often have obvious industrial or other sources, as well as in rural areas, where water or soil contamination may occur via long-range transport or from non-point sources.

While health concerns are often the focus of fish advisory development this document also provides information on health benefits of fish consumption and the economic and social impacts of various advisory strategies. Information on the benefits of fishing and fish consumption are provided to enable risk managers to evaluate the potential impacts of advisories; however, information on these topics is limited, often location-specific, and dependent on local characteristics. Quantitative cost-benefit analysis is not discussed in this volume; however, qualitative information on health benefits of fish and limited fishing revenue data are included. Information is also provided on potential societal impacts meriting consideration, such as traditional dietary patterns and religious and social traditions that rely on fishing and fish consumption. Although these types of impacts cannot be quantified or adapted to a balance sheet approach, they merit consideration in the development of advisories. The social, economic, and health impacts of advisories will vary depending upon the characteristics of the local population, and use of local information is encouraged.

A theme carried through this document is to utilize local information and participation where possible and to involve all potentially impacted parties in the decision-making process. It is hoped that the evaluation of potential impacts of fish advisories and broader public participation in decision-making will provide all affected parties access to policy making, and result in well-founded and widely accepted fish advisories.

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## GLOSSARY & ABBREVIATIONS

acute exposure	exposure at a relatively high level over a short period of time (minutes to a few days). (This is defined in IRIS as 24 hours or less; however, sources consulted utilized exposure periods of up to a few days. Consequently, the more encompassing definition is appropriate in reading this document.)
acceptable risk level	the maximum level of individual lifetime carcinogenic risk considered "acceptable" by risk managers.
agency	state, local, and tribal agencies and groups who have responsibility for managing risks associated with fish contamination are referred to as agencies in this text. These may include departments of environmental protection or health, tribal councils, and other types of regulatory and governing groups.
ATSDR	Agency for Toxic Substances and Disease Registry, U.S. Dept. of Health and Human Services, Public Health Service.
BW	body weight of an individual, expressed in kilograms (kg).
cancer potency	(often used interchangeably with slope factor) the slope of the dose-response curve in the low-dose region used with exposure to calculate the estimated lifetime cancer risk. Often expressed as risk per one milligram of exposure to the toxic chemical per kilogram body weight per day (mg/kg-d). Usually is calculated using the upper 95% confidence limit on the linear term in the linearized multistage (LMS) model.
chronic exposure	multiple exposures occurring over an extended period of time, or a significant fraction of the lifetime

developmental toxicity	adverse effects on the developing organism resulting from exposure prior to conception, during prenatal development, or postnatally up to the time of sexual maturation.
dose-response relationship	relationship between the exposure to an agent and changes in aspects of the biological system, apparently in response to that agent.
efficacy	refers to the degree to which a fish advisory program obtains compliance with advisories on the part of fish consumers.
endpoint	response measure in a toxicity study (e.g., liver damage, developmental toxicity, cancer).
EPA	United States Environmental Protection Agency.
exposure limits	a daily limit on exposure based upon health and toxicity data, which the reader may calculate, using the study data provided in this or other sources (mg/kg-day).
feasibility	refers to the match between the human, material, and financial resources required by an agency to carry out a program and the requirements of the program.
FDA	United States Food and Drug Administration.
fish	refers in this document to non-commercial fish from estuarine and fresh water sources, unless otherwise noted.
incidence	number of new cases of a disease within a specified time.
kg	kilogram, one thousand grams ( $10^3$ ), equivalent to 2.205 pounds (avoirdupois).
mg	milligrams, one thousandth ( $10^{-3}$ ) of a gram.
mg/kg-day	milligrams exposure per kilogram body weight of the exposed individual per day.

mutagenic	capable of inducing changes in genetic material (e.g., DNA).	
recreational fishers	non-commercial and non-subsistence fishers.	Synonymous with sport fishers in this document.
Reference Dose (RfD)	estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of adverse non-carcinogenic effects during a lifetime. Units are mg/kg-day.	
risk	the probability of injury, disease, or death under specific circumstances.	
SF	see cancer potency. (Not to be confused with safety factor approaches used in non-cancer analyses.)	
sport fishers	non-commercial and non-subsistence	fishers. Synonymous with recreational fishers in this document.
subsistence fishers	refers in this document to be people who rely on non-commercial fish as a major source of protein.	
threshold	dose or exposure below which a significant adverse effect is not expected.	